

### **REMARKS**

This amendment is in response to the Official Action dated December 28, 2009. Claims 2 and 9 have been amended. No claims have been added; no claims have been canceled. Claims 1-15 are now pending in this application. Claims 1, 4, 6, 10, 11, 13 and 14 are independent claims. Reconsideration and allowance is requested in view of the following remarks. Support for the amended claims can be found, for example, in paragraph [0117] of the specification, as represented in US. Pub. No. 2006/0247546

### **35 USC § 103 Rejections**

Claims 1-3 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lavie et al. (U.S. Patent Pub. No. 2003/0004423, hereinafter referred to as "Lavie '423") in view of Brown (U.S. Patent Pub. No. 20001/0011224, hereinafter referred to as "Brown '224"). Applicant respectfully traverses this rejection.

Claim 1 recites:

*An examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure, the apparatus comprising:*

*a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient;*

*an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;*

*an editor part for selecting a zone to be subjected to data processing among biological information including the airflow information and the electrocardiogram wave form of the subject patient through visual identification; and*

*an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part.*

Lavie '423 fails to disclose, teach or suggest "*an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form.*"

Moreover, Lavie '423 fails to disclose, teach or suggest "*an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part.*"

The Office Action, however, alleges these features can be found in paragraph [0077] of Lavie '423. This is wholly inaccurate.

Lavie '423 relates to a method and apparatus for the non-invasive detection of certain medical conditions, particularly certain sleep-state conditions, in an individual by monitoring the peripheral vascular system of the individual. Lavie '423 monitors the sleep state condition of an individual by using an external probe applied to a peripheral body location, such as the individual's finger or toe, for detecting changes in the peripheral vascular bed volume of the individual. The probe produces an output corresponding to changes in the peripheral arterial bed volume at the peripheral body location, and provides an indication of the sleep state condition of the individual. Preferably, the external probe used is one of the several non-invasive finger-probes for monitoring the peripheral vascular bed volume of the individual, and for translating the measurements to changes in peripheral arterial tone.

The Office Action states that an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured EKG wave form ([0077], [0113]). (Paragraph 4 of the Office Action.)

Paragraph [0077] of Lavie '423 states:

[0077] In addition to the above described sleep related breathing disorders, there exists a different class of breathing disorders which are not obstructive in nature but which are in fact related to aberrant central nervous system control of breathing during sleep. The phase relationship between the probe output and the alpha waves, as well as the phase relationship between the probe output and the variations in oxygen saturation, can provide important information about the type of the apnea as well as the associated hemodynamic changes.

Though Lavie '423 discloses that there exists a different class of breathing disorders which are not obstructive in nature but which are in fact related to aberrant central nervous system control of breathing during sleep, there is no mention for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form (EKG wave form). Indeed, Lavie '423 alludes that the phase relationship between the probe output and the alpha waves can provide important information about the type of the apnea but provides no means for analyzing or obtaining this information.

The office Action states that an output part for displaying or printing both of a transition of respiratory workflow and a transition of the enhanced state of sympathetic nervous of the subject patient (Fig. 13, 550). (Paragraph 4 of the Office Action.)

Paragraph [0117] of Lavie '423 states:

[0117] As further shown in FIG. 13, the outputs from the penile tumescence or rigidity monitoring device 510, together with the outputs from the other monitoring devices 412-520 for monitoring the sleep state condition of the patient, are converted to digital form by an A/D converter 530, and are fed to a processor 540. Processor processes this information and produces outputs to a monitor 550, a signal and/or alarm 560, a storage device 570, and a post-processor device 580.

There is **no mention** of an output part for displaying or printing both of (A) a transition of enhanced state of sympathetic nerves, and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part in Lavie '423.

- **Therefore, Lavie '423 fails to disclose, teach or suggest “an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form” and “an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part.”**

Brown '224 does not remedy the deficiencies of Lavie '423, as the various features recited above are also absent from Brown '224. For example, Applicant's claimed features of *“an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form,”* let alone *“an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part,”* are neither disclosed nor suggested by Brown '224.

Brown '224 relates to self-care health monitoring arrangements that enable a patient or other user to gather data important to a health management program and, if appropriate, provide that data to a healthcare professional. Brown '224 provides a useful system for healthcare maintenance in which the invention either serves as a peripheral device to (or incorporates) a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. Brown '224 provides program cartridge that adapts a microprocessor-based unit for operation with a glucose monitor (or, another type of health monitor). The microprocessor-based unit processes data supplied by the glucose monitor to supply signals for displaying relevant information on a display unit that may be included in the microprocessor-based unit or may be a separate unit such as a television or video display monitor.

Though Brown '224 provides useful data to a health care professional based on the input by the professional, there is no mention of for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form.

Furthermore, there is no mention of an output part for displaying or printing both of (A) a transition of enhanced state of sympathetic nerves, and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part in Brown '224.

Since even a combination of the relied upon references would still fail to yield the claimed invention, Applicant submits that a prima facie case of obviousness for claim 1 has not been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight, as there is no basis to combine the non-invasive means for measuring a particular sleep state condition of a patient of Lavie '423 with the modular microprocessor of Brown '224.

Furthermore, at least for the reason disclosed above, claims 2-3 overcome the combination of Lavie '423 and Brown '224 because they depend on independent claim 1 and thus incorporate the distinct features therein, as well as their separately recited patentably distinct features.

Accordingly, Applicant respectfully requests that the rejection of claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over Lavie '423 in view of Brown '224 be withdrawn.

Claims 4 and 6-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lavie '423 in view of Brown '224 and further in view of Krachman et al (*Comparison of Oxygen Therapy with Nasal Continuous Positive Airway Pressure on Cheyne-Stokes Respiration During Sleep in Congestive Heart Failure*, hereinafter referred to as "Krachman"). Applicant respectfully traverses this rejection.

Independent Claim 4 recites:

*A therapeutic system comprising: (1) an examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having a chronic heart failure, and/or use in ascertaining a therapeutic effect of the oxygen therapy; and (2) a supplying apparatus of an oxygen-enriched gas for respiration for the purpose of carrying out the oxygen therapy,*

*wherein the examination apparatus comprising:*

*a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence of magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring system attached on the body of the subject patient;*

*an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;*

*an editor part for selecting a zone to be subjected to data processing among biological information including the airflow information and the electrocardiogram wave form of the subject patient through visual identification; and*

*an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part.*

Claim 4 incorporates the features of independent claim 1, which are neither disclosed nor suggested by Lavie '423 in view of Brown '224, for the reasons stated above.

Krachman does not remedy the deficiencies of Lavie '423 in view of Brown '224, as the various features recited above are also absent from Krachman. For example, Applicant's claimed features of "*an analysis unit for analyzing the enhanced state of sympathetic nerves based on the*

*measured electrocardiogram wave form,” let alone “an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part,” are neither disclosed nor suggested by Krachman.*

Krachman compares the short-term effects of oxygen therapy and nasal CPAP therapy on CSR in a group of stable patient with server CHR.

There is **no mention** for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form in Krachman and there is **no mention** of an output part for displaying or printing a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part in Krachman.

Since even a combination of the relied upon references would still fail to yield the claimed invention, Applicant submits that a prima facie case of obviousness for claim 4 has not been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight, as there is no basis to combine the non-invasive means for measuring a particular sleep state condition of a patient of Lavie ‘423 with the modular microprocessor of Brown ‘224 with the comparison study of Krachman.

Independent Claim 6 recites:

*A method of selecting a patient for whom an oxygen therapy is effective among patients having a chronic heart failure comprising:*

*a step of attaching a non-implantable biological information monitoring system to the subject patient, wherein the monitoring system has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, and wherein the monitoring system is*

*constituted such that the subject patient can move in the state having the monitoring system attached on the body of the subject patient;*

*a step of measuring respiratory airflow and electrocardiogram wave form of the subject patient by using the monitoring system;*

*a step of analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;*

*a step of selecting a zone to be subjected to data processing among biological information of the subject patient through visual identification; and*

*a step of selecting a patient who exhibits both results that (A) the measured state of sympathetic nerves is an enhanced state, and (B) the transition of enhanced state of sympathetic nerves is found in conjunction with transition of respiratory airflow and an analysis result during the step of analysis within the zone selected,*

*wherein the oxygen therapy is to supply an oxygen-enriched gas for respiration of a patient.*

Independent claim 10 recites:

*A method of selecting a patient for whom an oxygen therapy is effective among patients having a chronic heart failure comprising:*

*a step of determining arterial oxygen saturation of a patient;*

*a step of attaching a non-implantable biological information monitoring system to the subject patient, wherein the monitoring system has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, and wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring system attached on the body of the subject patient;*

*a step of measuring respiratory airflow and electrocardiogram wave form of the subject patient by using the monitoring system;*



a step of analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;

a step of selecting a zone to be subjected to data processing among biological information of the subject patient through visual identification; and

a step of selecting a patient who exhibits the results within the zone selected of

(A) a measured arterial oxygensaturation not higher than a predetermined threshold value,

(B) a measured state of sympathetic nerves in an enhanced state and

(C) a transition of enhanced state of sympathetic nerves found in conjunction with a transition of respiratory airflow.

wherein the oxygen therapy is to supply an oxygen-enriched gas for respiration of a patient.

Independent claim 11 recite:

*A therapeutic method for chronic heart failure which comprises:*

*a step of attaching a non-implantable biological information monitoring system to the subject patient, wherein the monitoring system has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, and wherein the monitoring system is constituted such that the subject patient can move while having the monitoring system attached on the body of the subject patient;*

*a step of measuring respiratory airflow and electrocardiogram wave form of the subject patient by using the monitoring system;*

*a step of analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;*

a step of selecting a zone to be subjected to data processing among biological information of the subject patient through visual identification;

a step of selecting a patient exhibiting both results within the zone selected of (A) a measured state of sympathetic nerves in an enhanced state, and (B) a transition of enhanced state of sympathetic nerves found in conjunction with a transition of respiratory airflow; and

a step of administering an oxygen therapy for the selected subject patient,  
wherein the oxygen therapy is to supply an oxygen-enriched gas for respiration of a patient.

Independent claim 13 recites:

*A therapeutic method for chronic heart failure which comprises:*

*a step of determining arterial oxygen saturation of the subject patient,*

*a step of attaching a non-implantable biological information monitoring system to the subject patient,*

*wherein the monitoring system has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, and wherein the monitoring system is constituted such that the subject patient can move while having the monitoring system attached on the body of the subject patient;*

*a step of measuring respiratory airflow and electrocardiogram wave form of the subject patient by using the monitoring system;*

*a step of analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;*

*a step of selecting a zone to be subjected to data processing among biological information of the subject patient through visual identification;*

*a step of selecting a patient who exhibits the results within the zone selected*  
*of*  
*(A) a measured arterial oxygen saturation not higher than a predetermined*  
*threshold value,*  
*(B) a measured state of sympathetic nerves in an enhanced state, and*  
*(C) a transition of enhanced state of sympathetic nerves found in conjunction*  
*with transition of respiratory airflow; and*  
*a step of administering an oxygen therapy for the selected subject patient,*  
*wherein the oxygen therapy is to supply an oxygen-enriched gas for*  
*respiration of a patient.*

Independent claims 6, 10, 11 and 13 are method claims and include “*a step of analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form*” and “*a step of selecting a patient who exhibits results that (A) the measured state of sympathetic nerves is an enhanced state, and (B) the transition of enhanced state of sympathetic nerves is found in conjunction with transition of respiratory airflow.*”

At least these steps are neither disclosed nor suggested by Lavie ‘423 in view of Brown ‘224, for the reasons stated above.

Krachman compares the short-term effects of oxygen therapy and nasal CPAP therapy on CSR in a group of stable patient with server CHR. Krachman does not remedy the deficiencies of Lavie ‘423 in view of Brown ‘224, as the various features recited above are also absent from Krachman. Applicant’s claimed features of “*a step of analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form*” and “*a step of selecting a patient who exhibits results that (A) the measured state of sympathetic nerves is an enhanced state, and (B) the transition of enhanced state of sympathetic nerves is found in conjunction with transition of respiratory airflow*” are neither disclosed nor suggested by Krachman.

Since even a combination of the relied upon references would still fail to yield the claimed invention, Applicant submits that a prima facie case of obviousness for claim 4 has not

been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight, as there is no basis to combine the non-invasive means for measuring a particular sleep state condition of a patient of Lavie '423 with the modular microprocessor of Brown '224 with the comparison study of Krachman.

For the reasons stated above, claims 6, 10, 11, and 13 also are distinct from Lavie '423 in view of Brown '224 and further in view of Krachman (although claims 4, 6, 10, 11, and 13 should be interpreted solely based upon the limitations set forth therein). Furthermore, at least for the reason disclosed above, claims 7-9 and 12 overcome the combination of Lavie '423 in view of Brown '224 and further in view of Krachman because they depend on their respective independent claims and thus incorporate the distinct features therein, as well as their separately recited patentably distinct features.

Accordingly, Applicant respectfully requests that the rejection of claims 4 and 6-13 under 35 U.S.C. § 103(a) as being unpatentable over Lavie '423 in view of Brown '224 and further in view of Krachman be withdrawn.

Claim 5 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lavie '423 in view of Brown '224 in view of Krachman and further in view of Thomas et al. (U.S. Patent Pub. No. 2004/0144383, hereinafter referred to as "Thomas '383"). Applicant respectfully traverses this rejection.

Claim 5 depends from and thus incorporates the features of claims 1 which are neither disclosed nor suggested by Lavie '423 in view of Brown '224 and further in view of Krachman, for the reasons stated above.

Thomas '383 does not remedy the deficiencies of Lavie '423 in view of Brown '224 and further in view of Krachman, as the various features recited above are also absent from Thomas '383. For example, Applicant's claimed features of "*an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form,*" let alone "*an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a*

*transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part,”* are neither disclosed nor suggested by Thomas ‘383.

Thomas ‘383 offers redundant CO<sub>2</sub> monitoring capability as well as O<sub>2</sub> monitoring. The flow of CO<sub>2</sub> into the gas mixing chamber is controlled by a calibrated electrically actuated proportional valve, and is measured by a visually readable variable area glass flow meter. The monitoring of gas concentrations is further enhanced by the incorporation of a sensor that directly measures gas concentrations in the patient's blood. A transcutaneous monitor, such as a Sensormedics Microgas 7650, provides measurement of the partial pressure of both oxygen and CO<sub>2</sub> in the patient's arterial blood.

There is *no mention* for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form in Thomas ‘383.

Since even a combination of the relied upon references would still fail to yield the claimed invention, Applicant submits that a prima facie case of obviousness for claim 4 has not been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight, as there is no basis to combine the non-invasive means for measuring a particular sleep state condition of a patient of Lavie ‘423 with the modular microprocessor of Brown ‘224 with the comparison study of Krachman with the gas system measurement means of Thomas ‘383.

Furthermore, at least for the reason disclosed above, claim 5 overcomes the combination of Lavie ‘423 in view of Brown ‘224 in view of Krachman and further in view of Thomas ‘383 because it depend on independent claim 1 and thus incorporate the distinct features therein, as well as their separately recited patentably distinct features.

Accordingly, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Lavie ‘423 in view of Brown ‘224 in view of Krachman and further in view of Thomas ‘383 be withdrawn.

Claims 14 and 15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lavie '423 in view of Brown '224 and further in view of IBM DiskOnKey (8MB USB Memory Key – Overview, hereinafter referred to as “8MB Memory Overview”). Applicant respectfully traverses this rejection.

Claims 14 and 15 incorporate the features of claim 1 which are neither disclosed nor suggested by Lavie '423 in view of Brown '224, for the reasons stated above.

The 8MB Memory Overview simply discloses a portable and pocketable USB storage device. There is *no mention* for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form in this reference.

Accordingly, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Lavie '423 in view of Brown '224 and further in view of the 8MB Memory Overview be withdrawn.

## **Conclusion**

In view of the above amendment and remarks, applicant believes the pending application is in condition for allowance.

This response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

Application No. 10/551,668  
Amendment dated: March 29, 2010  
After Final Office Action of December 28, 2009

Docket No.: TEI-0135

### **Extensions of time**

Please treat any concurrent or future reply, requiring a petition for an extension of time under 37 C.F.R. §1.136, as incorporating a petition for extension of time for the appropriate length of time.

The Commissioner is hereby authorized to charge all required fees, fees under 37 C.F.R. §1.17, or all required extension of time fees.

### **Fees-general authorization**

The Commissioner is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm).

If any fee is required or any overpayment made, the Commissioner is hereby authorized to charge the fee or credit the overpayment to Deposit Account # 18-0013.

Dated: March 29, 2010

Respectfully submitted,

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